Public Health and Intelligence

minutes

NHS Scotland Public Benefit and Privacy Panel for Health and Social Care

13 September 2017

Lord Clerk Room – General Register House, Edinburgh

Present:
Brian Houston (Chair)
Prof Alison McCallum (AMcC)
Dr Angus Ferguson
Prof Danny McQueen (DMcQ)
Dr Stephen Pavis (SP)
Professor Abbe Brown (AB) by tele conference
Dr Kirsty Licence (KL)
Mr Kenneth McLean (KM)
Dr Emilia Crighton (EC)
Carole Morris, eDRIS representative (CM)
Ashley Gray, Panel Manager (AG)
Jenny Scott (JS)

Apologies:
Mr Gerry Donnelly
Mr David Knowles
Prof Helen Colhoun
Dr Corri Black
Dr Janet Murray
Dr George Fernie

1. Chair's Welcome

BH welcomed all to the PBPP Committee meeting and noted apologies received.

2. PBPP Application 1617-0265 Flaig: *'UK Biobank prospective cohort – longitudinal follow-up through linkage to health-related records in Scotland'*

AMcC introduced the application and summarised the main concerns on behalf of the Panel

AMcC explained that this proposal seeks to transfer large amounts of data, including CHI numbers, to University of Oxford. AMcC highlighted the following principle issues for discussion by the Panel and explained that there were some recommendations as well as practical issues to improve governance.

- Retention of CHI in the biobank rather than a unique key OR transfer of key for data to be linked within NHS Scotland
- Transfer of large volumes of data rather than creation and retention of data within Scotland with approval for release of specific datasets
- Privacy impact assessment for new holdings
- Data quality and integrity concerns associated with large databases that do not have specialised curation compared with building on specialised linked databases that have expert curation
- Lay and public involvement by means of a Public Panel (country specific) so that researchers can discuss proposed studies.

SP noted that the PBPP do not have a remit to comment on how the UK Biobank operates but should consider changes/clarification to the governance controls.
KL provided comments and advised that NHS Scotland are partners in Biobank and that a key should be used instead of providing CHI.

BH welcomed the applicants to the meeting to continue the discussion. In attendance were Mrs Robin Flaig (RF) and Dr Cathie Sudlow (CS)

AM explained that as NHS are partners in the venture there is a vested interested in the success and to maintain high standards of governance for both participants and non participants. AM further explained that Panel were aware that a lot of the datasets have quality issues and that some concerns have been raised regarding the transfer and manipulation of data. AM noted that there is no Privacy Impact Assessment and this requirement, like some of the other recommendations, go beyond the current landscape into GDPR 2018.

RF advised the Panel that the UK Biobank are currently working on a Privacy Impact Assessment and expect this to be prepared by the end of the year.

AM queried the establishment of a Public Panel as this is being increasingly requested for research in terms of demonstrating more active engagement.

CS explained that the UK Biobank has a number of engagement strands for participants including roadshows where local participations were invited to join. There have also been small panel discussions which are led by the Head of Communications as well as an annual meeting and newsletter. CS also confirmed that there is a participant resource centre available where general queries can be answered.

KL enquired as to what public participation there is in the decision making process
CS confirmed that there is an independent ethics/governance council with both participants and members of the public.

EC asked for further information on how patient identifiers are held versus the other patient information.
CS advised that separation of identifiers takes place at the University of Oxford, the database is anonymised and prepared for research access. Each research group receive different IDS and must sign MTA.

DM queried how this process is audited.

CS confirmed that there is an external risk and audit committee who carry out these assessments.

SP explained to CS and RF the process of assigning/providing a key to the CHI which would negate the need to the hold the CHI number and advised that this is the normal process for access.
CS advised that the UK Biobank is a dynamic population and to hold the CHI centrally is the best way to identify individuals and avoid double identification. CS explained it is vital that the database is scientifically robust and linkage correct through interaction with the CHI register.

AMcC highlighted that the conditions of commercial access to data is different and that normal process is for companies to receive tabulated information.
CS advised that it is clear in the consent form that commercial partners may access data.

AMcC queried the potential for the data to continue to be held by custodians and brought together for each purpose/project.
RF explained that the data has to come together to be accessed uniformly across the UK and to enable mapping across.
CS also noted that that model would reduce the number of projects.

BH thanked the applicants for their attendance and contribution to the discussion.

The Panel agreed that the application should be approved subject to a number of conditions:

- Exploration of how the services of the NHS Central Register could be used for flagging the cohort and therefore maintaining an updated list of CHI numbers that can be provided to the NHS for data linkage.
- Formalisation of the existing measures taken to ensure participant engagement by involving participants in the design and governance of UK Biobank going forward
- Commercial applicants are partnered with recognised academic institutions in accordance with PBPP standards.
- Updated Privacy Impact Assessment and participant consent form to ensure compliance with the requirements of the General Data Protection Regulation which comes into force in 2018
- Different research identifiers are used for each dataset so that datasets from different studies cannot be linked at a future date
- Additional data regarding participants' health, care and vital events is held securely and separately from the data gathered directly from participants during their participation in UK Biobank, being brought together to create specific datasets for which research ethics approval has been granted
- Formal agreement with the data custodian of any non-NSS dataset is obtained before these datasets are transferred
- These conditions are explicit in any material transfer agreements.

Action AMcC

3. PBPP Application 1617-0338 Palmer: '*SHARE- Central data transfer to SHARE in Health Informatics Centre (HIC) within FARR Dundee. (FD)*

KL introduced the application and summarised the main concerns on behalf of the Panel.

KL explained that the application seeks approval for the East Node Safe Haven (University of Dundee Health Informatics Centre (FD)) to be supplied with a central set of data for people resident in all NHS Board areas who are registered on SHARE, for the purpose of undertaking the cohort building for invitations to studies. FD would then provide the list of contacts for invitation for each study to the SHARE team.

The principle issues for discussion were highlighted as:

- The applicant has made a satisfactory case for the datasets outlined in the application but has not supplied a list of variables for each of those datasets.
- Additional justification for the routine collection of such an extensive and undifferentiated dataset on a large number of people, rather than targeting just those variables required to fulfil each request from a researcher.
- Updated PIL will be produced prior to the GDPR coming into force in May 2018 (within 12 months), to be reviewed for GDPR compliance, in particular around the issues of consent.
- Updated and comprehensive PIA which seeks support from local IG where required.
- The SHARE website https://www.registerforshare.org/ indicates that Caldicott Guardians are represented on all of the governance and advisory committees.
- Unclear how any conflict of interest regarding commercial funding would be managed if only one of the safe havens held SHARE data and thus benefited from cost recovery of studies.

AG confirmed to the Panel that the applicant had provided a number of documents in advance of the meeting (circulated with papers) to specifically address the issues highlighted including a list of data items, updated PIA and clarification regarding Caldicott Guardian involvement as per website.

BH welcomed the applicants to the meeting. In attendance for the discussion were Professor Brian McKinstry (BMcK), Professor Colin Palmer (CP) and Dr Tom Barlow (TB).

BMcK provided a brief introduction to SHARE as a register of individuals who have provided consent to be contacted for invitation to participate in medical research. The aims of the project are to optimise and facilitate wider participation in medical research in the Scottish population, and to accelerate the benefit of novel therapies to the Scottish public.
SHARE requests consent from participants to access the coded medical records of the registrants in order to establish if they may be suitable for particular studies. Currently the SHARE project only has access to data that is held within the four main regional Safe Havens corresponding to each R&D NHS Node and due to problems in terms of both capacity and skill sets SHARE are unable to identify people in a timely way using this method. Additionally the Safe Havens do not hold any data for the smaller boards in each Node therefore SHARE cannot facilitate participation in these other boards as individuals cannot be identified.
BMcK explained that SHARE can often be waiting for data for up to 5 months and as the MRC are funding the programme then there is need to continue to justify the existence of the register in terms of optimum performance.

TB advised that this application offers a temporary solution to enable SHARE to work and deliver what participants have signed up to when joining the register.

KL queried how the data requested as part of this application would be held in relation to the other data received and processed by HIC for different purposes.

CP confirmed that the databases will be separate.

EC advised that a diagram to illustrate the separation would be helpful.

KM asked whether it a more appropriate route would be to focus efforts on capacity building in the regional safe havens.

CP explained that there was a plan to increase capacity with the safe havens as part of another project but that capacity was only one of the issues with cohort building for SHARE.

AF enquired as to whether there had been any consultation with the participants of SHARE regarding this change from access to coded medical records at a regional level to national. BMcK advised not explicitly on this but SHARE do have patient representatives on the steering group.

DM wished to understand more about the audit mechanisms that are in place.
CP confirmed that there user access is monitored via access logs and that the institution where information is held is ISO accredited which meets the industry standard.

DM queried further regarding the internal audit process.
TB wished to state that the data doesn't leave the NHS.
CP advised that there is regular audit of usage in HIC and that there is a HIC IG Committee.

KL sought clarification regarding data sharing/service level agreements that are in place.
CP explained that Service Level agreements are in place with the safe havens.

BH thanked the applicants for attending the meeting.

Following the discussion the Committee were in agreement that the application should be approved subject to the following conditions:

- Submission of the final agreement between SHARE and HIC for the storage and processing of the whole of Scotland national dataset for SHARE. This should include confirmation of the systems in place to ensure separation of the national datasets provided for SHARE cohort building from other national datasets received by HIC for its wider role as a regional safe haven. A structural diagram would be helpful.
- PBPP approval is an interim solution, and the panel expects that work will progress to build the necessary infrastructure to facilitate and speed up searches across other regional safe havens and within the national safe haven so that transfer of whole population datasets is not an ongoing requirement beyond the approval period of this application
- A revised PIL should be submitted within 12 months of this approval, demonstrating compliance with new regulatory legislation, specifically GDPR
- The committee considers that, for such a large and growing project, there is limited public engagement and consultation with participants and potential participants. There are other models of excellent engagement from large data and biobank

repositiories and the committee suggests that SHARE engages with other projects to investigate and implement better ways of ensuring its public stakeholders are kept informed of, and have the opportunity to influence, its development.

Action KL

4. PBPP Application 1617-0151 Swallow: Improving diagnostic and care pathways in progressive supranuclear palsy (PSP) and corticobasal degeneration (CBD)

DM introduced the application and summarised the main concerns on behalf of the Panel.

DM explained that referral to the Committee was made on the basis that the applicant had not persuaded that the benefit of the proposed research project outweighs the potential risks to patient privacy.
DM advised that he was generally supportive the aims of the audit and the related research project, but in relation to points relating to security, level of non-consented personal information and lay representation it was felt that this application should be considered further by the Committee.

BH welcomed Dr Diane Swallow (DS) to the meeting to discuss her application.

DM outlined the main concerns to DS and invited comment from the applicant.

DS explained the purpose of the application is to gather evidence to inform clinical recommendations to improve diagnosis and patient care. At present access to care is not timely and all that is known currently about the patient group is general survival. This study wishes to examine care pathways and investigate further delays and difficulties in diagnosis. The audit will enable an accurate representation of the overall burden of the disease which can assist in healthcare planning and therefore it is important to locate people using multiple sources or the audit will not be informative. Some patient level identifiers are needed to avoid duplication of cases and these identifiers will not be used to contact patients but calculate region specific prevalence, age specific prevalence etc. The research study will seek explicit consent for sending/receiving information from participants.

The Committee queried further the process in place for holding identifiers.
DS explained that personal identifiable information will remain on the NHS servers at all times. University of Aberdeen will hold non-identifiable data.

SP enquired as to whether DaSH would be used for this project.
DS explained that this was not the proposal currently and that it was considered that this may add additional complexity to the data flow with another party being involved. DS advised that the methodology requires her to contact clinicians directly for information.

KL queried the return of cases using the SMR data and that there may be risk that there is high number of individual records returned that do not have this diagnosis based on the difficult in reporting the diagnosis using ICD10 codes.
DS acknowledged this point.

BH thanked DS for attending the meeting to discuss her application.

The Panel agreed that following the discussion with the applicant that they were fully persuaded of the potential public benefit of the study however there are outstanding methodological concerns that impact on issues of privacy and confidentiality that could be further improved. It was proposed that the applicant resubmits the application taking account of the following issues:

- Clear separation between the identifiers of the cases and their clinical information as early as possible, and before analysis
- Seek specific ethical advice in relation to the 'capture-recapture' methods being used for case ascertainment as this epidemiological approach may not be considered purely as 'audit'
- The consent process should be reviewed to ensure participants are fully informed about the nature of the data you will be collecting, and that it includes personal identifiers. It should be made clear to people how you are using their identifiers and how you will protect them.
- Consider wider engagement and consultation with the patient and carer group affected. This will assist in the review of the consent issues, as well as wider aspects of the study.
- Undertake some prior assessment of the ICD codes which will be requested from ISD to demonstrate that there will not be access to personal information on an excessive number of unaffected individuals